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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/827,887	04/06/2001	Charles D. Claude	ACSC-60087	5563

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EXAMINER

AHMED, SHEEBA

ART UNIT	PAPER NUMBER
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1773

DATE MAILED: 11/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/827,887

Applicant(s)

CLAUDE ET AL.

Examiner

Sheeba Ahmed

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-36 and 38-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-36 and 38-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/5/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Amendments to claim 36 have been entered in the above-identified application. Claims 1-32, 37, and 42-48 are cancelled. **Claims 33-36 and 38-41 are pending and under consideration.**

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 33-36, 38, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis-Lemessy et al. (US 6,139,525).

Davis-Lemessy et al. disclose a balloon catheter having a first polymeric component fusion bonded to a second polymeric component. The catheter has a first catheter part formed of a first polymeric material and a second catheter part formed of second polymeric materials fusion bonded to the first catheter part with the fusion bond containing a compatibilizing material during the fusion bonding. An inflatable balloon on a distal portion of the shaft has an interior in fluid communication with the shaft lumen. The balloon is secured to the catheter shaft by one or more fusion bonds as when a distal skirt of the balloon is secured to a tubular member of the catheter shaft by a distal fusion bond, a proximal skirt of the balloon is sealed about and secured to the catheter

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shaft by a proximal fusion bond at a point proximal to the distal fusion bond (Column 2, lines 9-40). The compatibilizing agent may be used alone or in combination with a surface treatment of one or both opposed surfaces. The surface treatment consists of a plasma treatment applied to either the surface of the balloon, surface of the shaft or both. The surface treatment acts by providing functional groups and increase surface area which facilitates fusion bond formation between the compatibilizing agent and the shaft and balloon. The preferred compatibilizing agent is a ethylene acrylic ester and an ethylene and acrylic acid copolymer (Column 3, lines 12-55). The strength of the fusion bond that the compatibilizing agent forms with the balloon and shaft is improved by surface treatment of the balloon and shaft (Column 5, lines 11-18).

Davis-Lemessy et al. do not teach that the acrylic layer of the compatibilizing agent is 10 to 150 nm in thickness.

However, it would have been obvious to optimize the thickness of the compatibilizing layer as taught by Davis-Lemessy et al. given that the thickness of a coating can be controlled to obtain specific properties and it is desirable to obtain a thin coating thickness for a bonding layer. Furthermore, with regards to the limitation that the acrylic layer is plasma polymerized, the Examiner would like to point out that the determination of patentability for product claims containing process limitations is based on the product itself and not on the method of production. If the product is the same or obvious from a product of the prior art, then the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985) and also see *MPEP* 2113. In this case, the product (i.e., the balloon catheter)

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is obvious despite the process limitation of plasma polymerizing the acrylic layer. In addition, Applicants are reminded that the structure implied by the process steps has been considered and does not impart distinctive structural characteristics to the final product.

3. Claims 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis-Lemessy et al. (US 6,139,525) in view of Okuda et al. (US 6,053,939).

Davis-Lemessy et al. disclose a balloon catheter having a first polymeric component fusion bonded to a second polymeric component. The catheter has a first catheter part formed of a first polymeric material and a second catheter part formed of second polymeric materials fusion bonded to the first catheter part with the fusion bond containing a compatibilizing material during the fusion bonding. An inflatable balloon on a distal portion of the shaft has an interior in fluid communication with the shaft lumen. The balloon is secured to the catheter shaft by one or more fusion bonds as when a distal skirt of the balloon is secured to a tubular member of the catheter shaft by a distal fusion bond, a proximal skirt of the balloon is sealed about and secured to the catheter shaft by a proximal fusion bond at a point proximal to the distal fusion bond (Column 2, lines 9-40). The compatibilizing agent may be used alone or in combination with a surface treatment of one or both opposed surfaces. The surface treatment consists of a plasma treatment applied to either the surface of the balloon, surface of the shaft or both. The surface treatment acts by providing functional groups and increase surface area which facilitates fusion bond formation between the compatibilizing agent and the

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shaft and balloon. The preferred compatibilizing agent is a ethylene acrylic ester and an ethylene and acrylic acid copolymer (Column 3, lines 12-55). The strength of the fusion bond that the compatibilizing agent forms with the balloon and shaft is improved by surface treatment of the balloon and shaft (Column 5, lines 11-18).

Davis-Lemessy does not disclose that the first layer (which corresponds to the first layer of the claimed invention) is an expanded PTFE having a node and fibril microstructure.

However, Okuda et al. teach that an expanded PTFE having a nodes and fibril microstructure has excellent biocompatibility (Column 1, lines 11-19).

Accordingly, it would have been obvious to one having ordinary skill in the art to replace the outer layer disclosed by Davis-Lemessy with a material having a nodes and fibril microstructure given that Okuda et al. specifically teach that such a microstructure provides excellent biocompatibility.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 33-36, 38, 39, and 41 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7, and 8 of U.S. Patent No. 6,946,173 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 1, 7, and 8 of U. S. Patent 6,946,173 B2 recite a balloon catheter having an elongated shaft having a proximal end, a distal end and an inflation lumen and a balloon having a first layer and a second layer fusion bonded to the first layer wherein the first layer is expanded PTFE and the first layer has a plasma polymerized functionally bonded to at least a section of the first layer.

Claims 1, 7, and 8 do not recite that the plasma-polymerized layer is 10 to 150 nm in thickness.

However, it would have been obvious to optimize the thickness of the first coating as taught by Davis-Lemessy et al. given that the coating thickness of a coating can be controlled to obtain specific properties and it is desirable to obtain a thin coating thickness for a bonding layer. Applicants are reminded that even though the instant application is the earlier filed application, only a one-way determination of obviousness is needed to support a double patenting rejection in the absence of a finding of an

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administrative delay on the part of the Office causing delay in prosecution of the earlier filed application; and that applicant could not have filed the conflicting claims in a single (i.e., the earlier filed) application.

Response to Arguments

5. Applicant's arguments filed on August 9, 2006 have been fully considered but they are not persuasive.

Applicants traverse the rejection of claims 33-36, 38, and 41 under 35 U.S.C. 103(a) as being unpatentable over Davis-Lemessy et al. (US 6,139,525) and the rejection of claims 39 and 40 under 35 U.S.C. 103(a) as being unpatentable over Davis-Lemessy et al. (US 6,139,525) in view of Okuda et al. (US 6,053,939) and submit that it would not have been obvious to one having ordinary skill in the art to optimize the thickness of the compatibilizing layer as taught by Davis-Lemessy. However, the Examiner disagrees and maintains her position that the thickness of the compatibilizing layer as taught by Davis-Lemessy et al. can be optimized to obtain specific properties and it is desirable to obtain a thin coating thickness for a bonding layer.

Applicants further argue that the requirements in Applicants claim 33 of a 10-150nm thickness acrylate or fragmented acrylate polymer film covalently bonded to at least a section of a first surface of the first layer is a structural limitation and that the plasma polymerized film results in a permanent surface modification. However, it is not clear to the Examiner how the structure implied by the process steps imparts distinctive structural characteristics to the final product.

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Lastly, the rejection of claims 33-36, 38, 39, and 41 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7, and 8 of U.S. Patent No. 6,946,173 B2 has not been addressed by the Applicants and is maintained.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheeba Ahmed whose telephone number is (571)272-1504. The examiner can normally be reached on Monday-Friday from 9am to 2pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carol Chaney can be reached on (571)272-1284. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

A handwritten signature in black ink, appearing to read 'Sheeba Ahmed', is written over the printed name.

Sheeba Ahmed
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October 28, 2006